

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: ILLYES PCT
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PRIORITY NO.: P0001103 FILED: 9 MARCH 2000
P0100911 FILED: 28 FEBRUARY 2001

FOR: APPARATUS FOR DOSAGE OF MEDICAMENTS

PRELIMINARY AMENDMENT

ATTN: BOX PCT APPLICATION
Assistant Commissioner of Patents
Washington, D.C. 20231

Dear Sir:

Preliminary to the initial Office Action, please amend the
above-identified application as follows:

IN THE SPECIFICATION:

On page 1, above line 1, please insert the following
paragraph:

--CROSS REFERENCE TO RELATED APPLICATIONS

Applicants claim priority under 35 U.S.C. §119 of HUNGARIAN
Application No. P0001103 filed on 9 MARCH 2000 and of HUNGARIAN
Application No. P0100911 filed on 28 FEBRUARY 2001. Applicants
also claim priority under 35 U.S.C. §120 of PCT/HU01/00028 filed
on MARCH 7, 2001. The international application under PCT
article 21(2) was published in English.--

10019972-110001

On page 1 of the Specification, following the words "Description of the state of art", please delete the second full paragraph and replace with the following:

--At the modern medical treatment there is very important for the physician to know the compliance of the patients concerning of the taking in the prescribed medicaments. Such apparatus is described in *U.S. Pat. No. 5,119,969* wherein a pill strip extends from the supply region along a dispensing path to a discharge position. The pills are dispensed by a manually actuated drive assembly. The pill strip is captured between a pair of toothed drive wheels not only driving but also perforating the pill strip. Thus, the contents of the dispensed pills strip can be easily accessed. To prevent unauthorized removal of pills a safety lock is used. A second example is disclosed in *U.S. Pat. No. 4,274,550* relating to a device comprising a container for the medicament, a feed means for feeding the said medicament, and a drive means exterior of the house of the device, and a transmission means between the drive means and the feed means. An other example of such a system is disclosed in *U.S. Pat. No. 4,733,797*. The disclosed assembly for storing and dispensing dosage units comprising: actuator means located at a manually accessible position to be operated by the user; plunger means adapted for reciprocal movement whereby to remove individual unit into dispensing orifice; and lever arms means connected at a first end thereof to said actuator means and at an opposite end thereof to an advancing means for advancing the strip of the dosages.--

In the Specification, please delete from page 3, line 28, to

page 4, line 26, and replace with the following:

--The inventive solution is an apparatus for dosing medicaments and controlling the taking in them, which apparatus consists of a storage unit, a dosing unit and a counter, wherein the medicament units (either tablets or capsules) to be dosed, packed into a medicament tape, are stored in the said storage unit and cylinders furthering said medicament tape are mounted onto the storage unit, and the said cylinders are mechanically coupled with a hand operated driver unit.

The characteristic feature of the solution according to invention is that the counter attaching to the apparatus, comprises a mechanic signal transmitter, an electronic sensor, an electronic evaluating unit, electrically connected to said sensor, an internal clock, and a memory unit, and the driver unit is coupled with the signal transmitter, which transmits a signal to the sensor at each dosing of medicament units. The coupling can be a direct or an indirect one, it can be established e.g. either by the shifting unit and/or by the axle.

The apparatus according to invention can be advantageously characterised by that it is equipped with a cutting unit, which serves to disjoint one by one the segments of the tape containing medicament units.

Another advantageous feature of the apparatus is that the driving unit is mechanically coupled with a cutting unit. and actuates it.

A further advantageous feature of the apparatus according to invention is that the driving unit is coupled with the cylinders through a stepping mechanism equipped with a position stabiliser and an inhibitor unit.

The apparatus according to invention can be advantageously characterised by that the stepping unit is equipped with lifting units, which lift the stepping one to an ineffective position and releasing ones which eliminate the lifting.

A following advantageous feature of the apparatus according to invention is that one of the cylinders is equipped with a unit winding up the cutting unit, namely with a cutting gearwheel, and with a unit releasing it. i. e. initiating the cut namely a cylinder lifting unit.--

A Marked-Up version of the amended pages of the Specification are attached hereto.

IN THE CLAIMS:

Please delete claims 1 to 9 and replace with claims 10 to 16 as follows:

10. An apparatus for dosing medicaments serving to control the taking in prescribed medicaments, which apparatus consists of a storage unit, a dosing unit and a counting one, wherein the medicament units (either capsules or tablets) to be dosed, packed in a medicament tape are stored in the storage unit and cylinders furthering said medicament tape are attached to the storage unit,

and the said cylinders are mechanically coupled with a manual driving unit, characterised by that, a counter (7) is attached to the apparatus, which comprises a mechanic signal transmitter (72), an electronic sensor (71), an electronic evaluating unit (74) electrically connected to said sensor, an internal clock (73) and a memory unit (75), and the driving unit (4) is coupled with the signal transmitter (72) issuing a signal to the sensor (71) at dosing of each tablet.

11. The apparatus according to Claim 10, characterised by that the apparatus is equipped with a cutting unit (9), which serves to cut off a segment of the medicament tape (50).

12. The apparatus according to Claim 11, characterised by that the driving unit (4) is coupled with the cutting unit (9) in a manner to control the latter.

13. The apparatus according to Claim 11, characterised by that the driving unit (4) is coupled with the cylinders (1) through a stepping unit (3) equipped with an inhibitor unit (6) stabilising the position.

14. The apparatus according to Claim 13, characterised by that the stepping unit (3) is equipped with lifting arms (33) which lift the inhibitor unit (6) into an ineffective position and with releasing arms (37) which eliminate the lifting.

15. The apparatus according to Claim 10, characterised by that at least one of the cylinders (1) is equipped with an unit winding up the cutting unit (9), namely with a cutting gear wheel

(15) and the stepping unit (3) is equipped with a unit eliminating the winding up of the cutting unit (9), namely a cylinder lifter (35).

16. The apparatus according to Claim 11, characterised by that the counter (7) is built up and fastened in the apparatus as an exchangeable unit.

REMARKS

By this Preliminary Amendment, the application has been amended to conform with U.S. practice, the cross-reference to related applications has been inserted on page 1.

The Specification has been amended as per the attachments.

Claims 1 to 9 have been canceled and new claims 10 to 16 have been added to eliminate the multiple dependency of the claims.

No new matter has been introduced. Entry of this Amendment is respectfully requested.

Respectfully submitted,
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Encl.: Amended pages of Specification

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I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10, on the date indicated above, and is addressed to the Ass't. Commissioner for Patents, Washington, D.C. 20231

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JC13 Rec'd PCT/PTO 09 NOV 2001

MARKED UP PAGES OF SPECIFICATION
PAGES 1, 3 AND 4

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APPARATUS FOR DOSAGE OF MEDICAMENTS

The field of the invention

An apparatus to dose medicaments and to control taking them, which apparatus consists of a tablet or capsule storage unit, a dosage unit and a counting unit, as well.

Description of the state of art

[Apparatuses serving for dosage medicament tablets or similarly shaped products, like table dosing apparatuses of saccharin or lemon salt are well-known for a long time past. These dosage apparatuses are based on the principle, that a cassette is arranged under a container which holds tablets in bulk mass, and the cassette is movable against a spring force. The cassette is open both on the upper and lower sides. A pill or tablet falls from the container into the cassette. The cassette is moved into the other sector of dosing apparatus, where the bottom of cassette has an opening, the pill or tablet falls out. A treatment of a patient with prescribed medicaments requires an apparatus of higher quality and accuracy. Such apparatus is described in the patent application PCT/US96/0387, which comprises an event counter. The characteristic feature of this apparatus is that a display unit can be cyclically operated in an on and an off status. The counting is coupled with the electric switching on and off the apparatus. The patient carries the apparatus with himself and it counts and records all the events occurring during the treatment. The apparatus has a disadvantage that the dosage of medicament and the counting are not interlocked.] new paragraph inserted

No one of the known apparatuses affords a solution to control, how the patient cooperates with his physician and whether he takes the prescribed medicament in at the prescribed time. If he deviates from the prescription, how long e. g. the deviation time is. Such data are necessary both in the viewpoint of the treatment and for recognition of efficiency of the applied medicament, as well.

We recognised, that the stepwise movement of tape can be performed by the length of one medicament unit at each time even in the simplest embodiment without cutting unit.

5 A cutting unit becomes automatically wound up at the movement of the shifting unit and it is released at the end of movement by a prescribed length and cuts the tape in another advanced embodiment of the apparatus.

It belongs to the recognitions, that the separate furthering and cutting makes possible a relatively slow furthering followed by an instantaneous cutting. The furthering of the tape and cutting of a medicament unit are, however not
10 simultaneous by this way but one after the other, nevertheless they are bound inseparably together by means of a simple automatic mechanism. It is required that if a furthering has begun, it should not be ceased, but it should be performed anyway on the whole designed length. The movements on partial distances can cause an erroneous positioning of the tape and the cutting can destruct the tablets.
15 We recognised furthermore, that the above mentioned partial movements caused by a partially actuated shifting unit can be eliminated, if the shifting unit rests in the reached position and a following movement can only complete the previous one.

All the embodiments carried out on the base of the above mentioned recognitions
20 can comply with the aim set above, but they have different reliability. It should be considered in any case, whether a simpler, consequently cheaper apparatus or a more exigent, consequently more expensive one should be chosen.

A supplement of the inventive recognitions is, that several advantages can be obtained if an electronic counter, which registers the patient's co-operative
25 behaviour (compliance), is attached to the system as an exchangeable unit. The physician's evaluation becomes easier and the counter becomes reusable even in the case, when the dosing unit used only once and then disposed.

[The inventive solution is an apparatus for dosage of medicaments and control of taking in them, the apparatus based on the above mentioned recognitions consists
30 of a storage unit, which stores the capsules or tablets to be dosed, a dosing unit and a counter. The characteristic feature of the solution according to invention is

that furthering cylinders are mounted onto the container which stores the medicament units (either tablets or capsules, packed into a tape shaped blister pack), and the said cylinders are mechanically coupled with a hand operated driver unit.

- 5 The apparatus according to invention can be advantageously characterised by that it is equipped with a cutting unit, which serves to disjoint one by one the segments of the tape containing medicament units.

Another advantageous feature of the apparatus is that the counter comprises a mechanic signal transmitter, an electronic sensor, an internal clock and a memory
10 unit.

A further advantageous feature of the apparatus according to invention is that the driver unit is coupled with the signal transmitter, which transmits a signal to the sensor at each dosing of medicament units. The coupling can be a direct or an indirect one, it can be established e.g. either by the shifting unit and/or by the axle.

- 15 The apparatus according to invention can be advantageously characterised by that the driving unit is mechanically coupled with a cutting unit. and actuates it.

A following advantageous feature of the apparatus according to invention is that the driving unit is coupled with the cylinders through a stepping mechanism equipped with a position stabiliser and an inhibitor unit.

- 20 The embodiment with inhibitor unit can be advantageously characterised that the stepping unit is equipped with lifting units, which lift the stepping one to an ineffective position and releasing ones which eliminate the lifting.

A further advantageous embodiment of the apparatus according to invention can be characterised that one of the cylinders is equipped with a unit winding up the
25 cutting unit, namely with a cutting gearwheel, and with a unit releasing it. i. e.

initiating the cut namely a cylinder lifting unit.] *new paragraphs inserted*

- Finally, the apparatus according to invention can be advantageously characterised that the counter is exchangeable by its shape and dimensions, and it is mounted
30 onto apparatus using a known in itself solution and can be simply inserted, taken out or changed.